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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,374	08/25/2006	Tomoyuki Nemoto	20692/0205266-US0	3271

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EXAMINER	
LISTVOYB, GREGORY	
ART UNIT	PAPER NUMBER
1796	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,374	NEMOTO ET AL.	
	Examiner	Art Unit	
	GREGORY LISTVOYB	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/31/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3,5-11 rejected under 35 U.S.C. 103(a) as being unpatentable over Jun (JP 2003-012834) herein Jun or Rosenbaum et al (WO02/087877, cited with corresponding US 7144634) herein Rosenbaum.

Jun discloses a biodegradable flexible film, comprising as a main component a lactic acid resin composition comprising:

a poly(DL-lactic acid) of Molecular weight range of 50000-400000 (see line 0018) in which the proportion of L-isomer and D-isomer is 90:10 (see line 0022) and a 5-50% of plasticizer (see Abstract, line 0029), the lactic acid resin composition, wherein a value of the storage modulus (E') at 20°C is in the range of 20-700 MPa as measured at a frequency of 10 Hz by the dynamic viscoelasticity testing method from Method A of JIS K-7198 (see line 0049),

and a peak value of the loss tangent (tan delta) is in the range of 0.2 to 0.8 (see claim 2).

In reference to Claim 5, Jun teaches Hm-Hc difference of 10J/g or more (see Table 2).

Note that Jun teaches proportion of L-isomer and D-isomer is 85:15 (see Comparative Example 2, where he uses the same lactic acid as one of the Application, i.e. Cargil Dow Nature Works 4060D, see line 0059). However, the Storage Module value in this case is 65 MPA (see Table 2), which is outside of the claimed range.

Storage Module value characterizes elastic properties of the polymer and depends on its structure, molecular weight (increased Mw leads to decreasing E') and type and amount of plasticizer (the latter increases loss modulus and decreases storage modulus).

Changing L/D ratio in a polymer is one of the methods to achieve required properties such as: flexibility, orientation degree, tensile strength (especially in MD direction), etc.

Thus, mechanical characteristic of the film can be varied by both L/D isomer ratio and the amount of plasticizer present. The disadvantage of having excessive amount of plasticizer is its bleeding.

Therefore, it would have been obvious to a person of ordinary skills in the art to vary content of L-lactic isomer in a polylactic acid from 100 to 80% in order to achieve a required balance between such film parameters as flexibility, orientation degree, tensile strength (especially in MD direction), etc.

Rosenbaum teaches plasticized (glycerol fatty acid ester, the same as one of the Application, see Abstract) polylactic acid film, where content of L-Lactic acid units is within the range of 80-100% (see Column 2, line 40).

Rosenbaum teaches that D-lactic acid monomers used to decrease crystallinity degree.

Regarding Claims 1-3, 5-9, Jun or Rosenbaum do not teach the properties of the film (especially Storage modulus at 40 and 100C) within the claimed range. However, it would be obvious to a person of ordinary skills in the art that film flexibility at given polymer and plasticizer structure primarily depends on the amount of plasticizer used (a result-effective variable) (see Jun, line 0035).

A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) (see also MPEP 2144.05). See

also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) (prior art suggested proportional balancing to achieve desired results in the formation of an alloy).

In reference to new claims 10-11, Jun teaches an aliphatic-dicarboxylic-acid alkyl ester as a plastisizer (see line 0032).

Response to Arguments

Applicant's arguments filed 9/08/2008 have been fully considered but they are not persuasive.

Applicant argues that Jun's film has lower values of storage modulus compare to ones of the application examined.

As Examiner states in the Non-Final rejection on 5/08/2008, Storage modulus depends on L/D isomer ratio of polylactic acid along with plastisizer content. Since Jun teaches proportion of L-isomer and D-isomer is 85:15 (see Comparative Example 2, where he uses the same lactic acid as one of the Application, i.e. Cargil Dow Nature Works 4060D, see line 0059), the difference between Jun and Applicant is only a plasticizer content, which is a result-effective variable.

A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum

or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

The same argument is applicable to Rosenbaum et al.

Applicant argues that even at the same L/D ratio in polylactic acid and amount of plasticizer (see Table of the Response), storage module value can be radically different especially at high temperatures.

In the Specification Applicant teaches that thermal history can play a significant role in crystallization degree of the film and therefore, storage modulus at high temperatures (see line 0122). Applicant teaches that Hm-Hc value of 20 J/g is desirable in order to achieve above storage module profile.

Jun teaches Hm value of 10-50J/g and thermal treatment equivalent to one of the Application (see line 0043). Therefore, storage modulus profile of Jun film is expected to be the same as one of the Application.

Rejection based on 35 USC 112(1) is withdrawn due to the claim amendments.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGORY LISTVOYB whose telephone number is (571)272-6105. The examiner can normally be reached on 10am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on 571-272-1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rabon Sergent/
Primary Examiner, Art Unit 1796

GL